**Submitter :** **Mr. John Manter**

**Date:** **09/16/2005**

**Organization :** **Mr. John Manter**

**Category :** **Other Health Care Professional**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Same day rule
Please allow hospitals to bill repetitive services with or without other OPPS codes on the same day.

**Submitter :** Mrs. Kamenna Lee

**Organization :** American Red Cross

**Category :** Health Care Industry

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

Re: Blood and Blood Products.

See attached.

CMS-1501-P-614-Attach-1.PDF

#614

American Red Cross

*Together, we can save a life*

September 16, 2005

The Honorable Mark McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

**RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [70 FR 141, July 25, 2005; Docket # CMS-1501-P]; Blood and Blood Products**

Dear Administrator McClellan:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Centers for Medicare & Medicaid Services' (CMS or agency) proposed rule titled "*Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*" (hereafter, referred to as the proposed rule).

The Red Cross is an independent organization that is organized and exists as a nonprofit, tax-exempt, charitable organization pursuant to a charter granted to it by the United States Congress. The Red Cross, through its 35 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. The plasma donated by Red Cross's volunteers is recovered from whole blood and further processed or fractionated into plasma derivatives. The Red Cross is committed to the safety of donors and patients, and to meet the best interests of the public we serve.

All patients, including Medicare beneficiaries which represent the largest group of transfusion recipients[1], need to have access to the safest and most immediately available blood supply possible. The Red Cross would like to acknowledge the progress made in recent years through the thoughtful consideration given by both CMS and the Advisory Panel on Ambulatory Payment Classification (APC) Groups (*The Panel*) to the concerns

[1] Analysis of National Hospital Discharge Survey 1999 and 2000 data by PAREXEL International Corporation.

raised by the Red Cross and others in the blood banking industry. In particular, the Red Cross is truly pleased that *The Panel* consistently supported recommendations for more comprehensive blood billing guidance and that CMS issued such guidance this spring (CMS Transmittals 496 and 18, dated March 4, 2005).

CMS and *The Panel* also have responded to concerns about the level of Medicare reimbursement for blood products. Most recently, in the calendar year 2006 Medicare hospital outpatient prospective payment system (OPPS) proposed rule, CMS has addressed the concerns expressed previously that declining reimbursement for low-volume products may reflect insufficient data rather than actual hospital cost trends.

The Red Cross appreciates CMS's longstanding acknowledgment of the importance of adequate reimbursement for maintaining an available and safe blood supply, which the agency expressed in the original April 7, 2000, OPPS final rule by stating, "The safety of the nation's blood supply is a major concern of the Department of Health and Human Services, and we want to encourage appropriate testing and follow-up care."[2] CMS again acknowledges "the need to protect beneficiaries' access to a safe blood supply"[3] in the 2006 OPPS proposed rule.

However, the Red Cross was concerned to see proposed decreases in reimbursement rates for key blood products, for which our internal data show that the acquisition costs faced by hospitals did not decrease, but in fact increased in the past year.

Over the past several years, the Red Cross's comments to CMS and *The Panel* consistently have highlighted the growing complexity and the resulting rise in costs of blood banking operations. An increasingly challenging aspect of blood bank operations is the recruitment of new, qualified, younger blood donors to meet hospital demand and replace aging, repeat blood donors. Donor recruitment and retention are becoming significantly costlier, driving up the expenses associated with making blood available to patients in need.

Costly federally mandated requirements and recommendations by the U.S. Food and Drug Administration and its advisory committees also have significant impact on the increasing costs of blood products. The introduction of new technologies and tests, while improving the availability and safety of blood products, also leads to higher complexity and greater costs. Just one current example is the recently approved Gambro protocol for a seven-day platelet product. Although our hospital customers indicate overwhelming demand for such a product due to ongoing issues with availablity of single donor platelets, the product's potential introduction and the required post-marketing study likely may result in increased costs of the blood products provided.

## RECOMMENDATIONS

The Red Cross has two recommendations:

---

[2] 65 *Federal Register* 18449.
[3] 70 *Federal Register* 42741.

- **Recommendation 1:** We strongly urge CMS to accept *The Panel's* recent recommendation to use 2005 APC payment rates for blood products as a floor for payment in 2006.

- **Recommendation 2:** We recommend that CMS update its OPPS blood billing guidelines on at least an annual basis.

We discuss each of these recommendations in detail below.

**Recommendation 1: Use 2005 APC Payment Rates for Blood Products as a Floor for Payment in 2006**

The Red Cross provides approximately 45 percent of the nation's blood supply, and we are concerned when we see that the OPPS median costs of blood products (as based on Medicare hospital outpatient claims data) have decreased, when we know that the prices at which hospitals purchase blood products from us actually have increased.

As an example, the proposed 2006 APC payment rate for leukoreduced red blood cells (HCPCS code P9016), $162.42, represents a 2-percent decrease from the 2005 rate of $165.70. This decrease in payment is of particular concern because Red Cross data show that the price of leukoreduced red blood cells has only increased in recent years. Just in the first half of 2005, our average cost of a unit of leukoreduced red blood cells increased 5 percent compared to the first half of 2004, only widening an already significant gap between costs and reimbursement for this product. Specifically, the proposed 2006 payment rate would reimburse hospitals for only 74 percent of their product acquisition costs.

Leukoreduced red blood cells not only represent the single largest-volume blood product acquired by hospitals, but also are among the 15 most frequently billed drugs and biologicals under OPPS.[4] The high utilization of this product means that the widening gap between costs and reimbursement has significant financial impact on hospitals, and therefore, on Medicare beneficiaries' long-term access to these products.

Additionally, given that CMS is committed to setting 2006 APC payment rates for most separately payable drugs and biologicals based on hospital acquisition costs, we find it concerning that the proposed payment rate for leukoreduced red blood cells is well below hospitals' costs for this product. Although blood products are not recognized as specified covered outpatient drugs by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), we believe that it is equally important to ensure that blood product payment rates are set at levels that will allow hospitals to cover their costs and continue to provide beneficiaries with adequate access to blood and blood products.

Low-volume blood products also represent a significant area of concern. In 2005, the APC payment rates for several low-volume blood products decreased from their 2004 levels.

---

[4] Based on analysis of total billed days as listed in "Median Costs for Drugs, Biologicals, and Radiopharmaceuticals" file used to develop the 2006 OPPS proposed rule. Available at: http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp.

CMS responded to the concerns of the blood banking community and adjusted its APC rate-setting methodology for these products, reducing the extent of the payment decreases as compared to the changes first announced in the 2005 OPPS proposed rule. However, we remain concerned about the payment levels for these products, as the proposed rates for 2006 would allow additional decreases in payment of up to 10 percent.

The Panel shared our concerns about these products at its September 2004 meeting when it recommended that "CMS freeze payment rates for the low-volume blood products noted in Table 31 of the Notice of Proposed Rulemaking (NPRM) at the 2004 level for 2005."[5] Because CMS ultimately did not freeze the APC payment rates for these products for the 2005 OPPS update, the current payment rates for the products are lower than their 2004 levels. We are concerned that further decreases as proposed by CMS would be difficult for hospitals to bear and could compromise beneficiary access to these products.

At its August 2005 meeting, *The Panel* issued the following recommendation in response to our concerns (as well as similar concerns expressed by AABB) regarding the proposed payment decreases for certain blood products:

> *The Panel recommends* that CMS use its 2005 payment rates as the floor for payment rates for all blood and blood products for 2006; specifically, CMS should pay the greater of 1) the simulated median as determined by 2004 data or 2) the 2005 payment median.[6]

**The Red Cross strongly urges CMS to accept *The Panel*'s recommendation and use 2005 APC payment amounts for blood products as a floor for 2006 payment amounts.**

**Recommendation 2: Update the OPPS Blood Billing Guidelines on at Least an Annual Basis**

The Red Cross truly appreciates CMS's issuance of comprehensive OPPS blood billing guidelines earlier this year. Since the guidelines were released in March 2005, the Red Cross has actively educated hospitals on the guidelines through our reimbursement email service and at reimbursement seminars throughout the country. While hospitals also are appreciative of the new guidelines, we consistently find that many providers remain confused about key aspects of blood billing.

We have received numerous inquiries from hospitals who are unclear as to whether they must follow the new blood coding requirements (involving reporting the BL modifier, as well as both the 380 and 390 revenue codes). Since these hospitals obtain their blood from the Red Cross, they pay only for blood processing and handling (rather than the blood itself) and, therefore, are not subject to these new requirements. This is true for the majority of U.S. hospitals, even for those who obtain their blood from suppliers other than the Red Cross.

---

[5] Report of *The Panel*, September 1-2, 2005, p. 5, available at: http://www.cms.hhs.gov/faca/apc/090104minutes.pdf

[6] Report of *The Panel*, August 17-18, 2005, p. 13, available at: http://www.cms.hhs.gov/faca/apc/Minutes09-14-2005.pdf

For example, the section of Transmittal 496 that outlines the new requirements begins with the following heading: "New Modifier and Billing Requirements When an OPPS Provider Purchases Blood or Blood Products from a Community Blood Bank ..."[7] Based on this language, it is understandable that a hospital who obtains blood from the Red Cross might think that they are "purchasing blood products from a community blood bank," even though they actually are paying only for processing. Upon reading the guidelines, hospitals may conclude that they must change their blood billing practices in order to comply with the new coding requirements.

Given that the new coding requirements affect only a small percentage of hospitals, we believe that it is important for CMS to clarify this issue as soon as possible. At the August 2005 meeting of *The Panel*, John Carlsen, a principal at Covance Market Access Services who conducts the Red Cross reimbursement seminars and assists Red Cross hospital customers with reimbursement issues, suggested that CMS update its OPPS blood billing guidelines on an annual basis.[8] We agree with this suggestion and encourage CMS to use its first update of the guidelines as an opportunity to clarify that the new coding requirements only apply to hospitals that pay for the blood itself. We also ask that CMS include clarification on this subject in the calendar year 2006 OPPS final rule. Additionally, the Red Cross is collaborating with others in the blood banking community to develop more comprehensive recommendations on how the blood billing guidelines could be improved and clarified; we expect to provide these recommendations to CMS in the near future.

**The Red Cross recommends that CMS update its OPPS blood billing guidelines on at least an annual basis.**

## SUMMARY OF RECOMMENDATIONS

In summary, the Red Cross praises CMS for its appreciation of the challenges hospitals have faced with inadequate reimbursement levels, as well as for issuing comprehensive blood billing guidelines this spring. We hope that these guidelines ultimately will improve the quality and accuracy of hospital claims data for blood products; however, due to the timing of the guidelines (March 2005), any improved claims data would not be available for rate-setting until the 2007 OPPS update.

In the meantime, we urge CMS to: (1) use 2005 APC payment amounts for blood products as a floor for payment in 2006, and (2) update its OPPS blood billing guidelines on at least an annual basis. The Red Cross would like to thank CMS for its considertion of these important issues.

---

[7] CMS Transmittal 486, March 4, 2005, p. 3, available at: http://www.cms.hhs.gov/manuals/pm_trans/R496CP.pdf

[8] Report of The Panel, August 17-18, 2005, p. 13, available at: http://www.cms.hhs.gov/faca/apc/Minutes09-14-2005.pdf

The Red Cross appreciates this opportunity to provide public comments on the proposed rule. If you have any further questions or require follow-up, please contact Kamenna Lee, Director, Hospital Sales and Marketing, at 202-303-5443 (phone), 202-303-0078 (fax), or leekam@usa.redcross.org (e-mail).

Sincerely,

Kamenna Lee
Director, Hospital Sales and Marketing
Biomedical Services
American Red Cross

**Submitter :** Dr. Thomas Green

**Organization :** Swedish Urology Group

**Category :** Physician

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Mrs. Kamenna Lee **Date:** 09/16/2005

**Organization :** American Red Cross

**Category :** Health Care Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

Re: Blood and blood products.

See attached.

CMS-1501-P-616-Attach-1.PDF

#616

American Red Cross

*Together, we can save a life*

September 16, 2005

The Honorable Mark McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

**RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [70 FR 141, July 25, 2005; Docket # CMS-1501-P]; Blood and Blood Products**

Dear Administrator McClellan:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Centers for Medicare & Medicaid Services' (CMS or agency) proposed rule titled "*Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*" (hereafter, referred to as the proposed rule).

The Red Cross is an independent organization that is organized and exists as a nonprofit, tax-exempt, charitable organization pursuant to a charter granted to it by the United States Congress. The Red Cross, through its 35 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. The plasma donated by Red Cross's volunteers is recovered from whole blood and further processed or fractionated into plasma derivatives. The Red Cross is committed to the safety of donors and patients, and to meet the best interests of the public we serve.

All patients, including Medicare beneficiaries which represent the largest group of transfusion recipients[1], need to have access to the safest and most immediately available blood supply possible. The Red Cross would like to acknowledge the progress made in recent years through the thoughtful consideration given by both CMS and the Advisory Panel on Ambulatory Payment Classification (APC) Groups (*The Panel*) to the concerns

[1] Analysis of National Hospital Discharge Survey 1999 and 2000 data by PAREXEL International Corporation.

raised by the Red Cross and others in the blood banking industry. In particular, the Red Cross is truly pleased that *The Panel* consistently supported recommendations for more comprehensive blood billing guidance and that CMS issued such guidance this spring (CMS Transmittals 496 and 18, dated March 4, 2005).

CMS and *The Panel* also have responded to concerns about the level of Medicare reimbursement for blood products. Most recently, in the calendar year 2006 Medicare hospital outpatient prospective payment system (OPPS) proposed rule, CMS has addressed the concerns expressed previously that declining reimbursement for low-volume products may reflect insufficient data rather than actual hospital cost trends.

The Red Cross appreciates CMS's longstanding acknowledgment of the importance of adequate reimbursement for maintaining an available and safe blood supply, which the agency expressed in the original April 7, 2000, OPPS final rule by stating, "The safety of the nation's blood supply is a major concern of the Department of Health and Human Services, and we want to encourage appropriate testing and follow-up care."[2] CMS again acknowledges "the need to protect beneficiaries' access to a safe blood supply"[3] in the 2006 OPPS proposed rule.

However, the Red Cross was concerned to see proposed decreases in reimbursement rates for key blood products, for which our internal data show that the acquisition costs faced by hospitals did not decrease, but in fact increased in the past year.

Over the past several years, the Red Cross's comments to CMS and *The Panel* consistently have highlighted the growing complexity and the resulting rise in costs of blood banking operations. An increasingly challenging aspect of blood bank operations is the recruitment of new, qualified, younger blood donors to meet hospital demand and replace aging, repeat blood donors. Donor recruitment and retention are becoming significantly costlier, driving up the expenses associated with making blood available to patients in need.

Costly federally mandated requirements and recommendations by the U.S. Food and Drug Administration and its advisory committees also have significant impact on the increasing costs of blood products. The introduction of new technologies and tests, while improving the availability and safety of blood products, also leads to higher complexity and greater costs. Just one current example is the recently approved Gambro protocol for a seven-day platelet product. Although our hospital customers indicate overwhelming demand for such a product due to ongoing issues with availablity of single donor platelets, the product's potential introduction and the required post-marketing study likely may result in increased costs of the blood products provided.

## RECOMMENDATIONS

The Red Cross has two recommendations:

---

[2] 65 *Federal Register* 18449.
[3] 70 *Federal Register* 42741.

- **Recommendation 1:** We strongly urge CMS to accept *The Panel's* recent recommendation to use 2005 APC payment rates for blood products as a floor for payment in 2006.

- **Recommendation 2:** We recommend that CMS update its OPPS blood billing guidelines on at least an annual basis.

We discuss each of these recommendations in detail below.

**Recommendation 1: Use 2005 APC Payment Rates for Blood Products as a Floor for Payment in 2006**

The Red Cross provides approximately 45 percent of the nation's blood supply, and we are concerned when we see that the OPPS median costs of blood products (as based on Medicare hospital outpatient claims data) have decreased, when we know that the prices at which hospitals purchase blood products from us actually have increased.

As an example, the proposed 2006 APC payment rate for leukoreduced red blood cells (HCPCS code P9016), $162.42, represents a 2-percent decrease from the 2005 rate of $165.70. This decrease in payment is of particular concern because Red Cross data show that the price of leukoreduced red blood cells has only increased in recent years. Just in the first half of 2005, our average cost of a unit of leukoreduced red blood cells increased 5 percent compared to the first half of 2004, only widening an already significant gap between costs and reimbursement for this product. Specifically, the proposed 2006 payment rate would reimburse hospitals for only 74 percent of their product acquisition costs.

Leukoreduced red blood cells not only represent the single largest-volume blood product acquired by hospitals, but also are among the 15 most frequently billed drugs and biologicals under OPPS.[4] The high utilization of this product means that the widening gap between costs and reimbursement has significant financial impact on hospitals, and therefore, on Medicare beneficiaries' long-term access to these products.

Additionally, given that CMS is committed to setting 2006 APC payment rates for most separately payable drugs and biologicals based on hospital acquisition costs, we find it concerning that the proposed payment rate for leukoreduced red blood cells is well below hospitals' costs for this product. Although blood products are not recognized as specified covered outpatient drugs by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), we believe that it is equally important to ensure that blood product payment rates are set at levels that will allow hospitals to cover their costs and continue to provide beneficiaries with adequate access to blood and blood products.

Low-volume blood products also represent a significant area of concern. In 2005, the APC payment rates for several low-volume blood products decreased from their 2004 levels.

---

[4] Based on analysis of total billed days as listed in "Median Costs for Drugs, Biologicals, and Radiopharmaceuticals" file used to develop the 2006 OPPS proposed rule. Available at: http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp.

CMS responded to the concerns of the blood banking community and adjusted its APC rate-setting methodology for these products, reducing the extent of the payment decreases as compared to the changes first announced in the 2005 OPPS proposed rule. However, we remain concerned about the payment levels for these products, as the proposed rates for 2006 would allow additional decreases in payment of up to 10 percent.

The Panel shared our concerns about these products at its September 2004 meeting when it recommended that "CMS freeze payment rates for the low-volume blood products noted in Table 31 of the Notice of Proposed Rulemaking (NPRM) at the 2004 level for 2005."[5] Because CMS ultimately did not freeze the APC payment rates for these products for the 2005 OPPS update, the current payment rates for the products are lower than their 2004 levels. We are concerned that further decreases as proposed by CMS would be difficult for hospitals to bear and could compromise beneficiary access to these products.

At its August 2005 meeting, *The Panel* issued the following recommendation in response to our concerns (as well as similar concerns expressed by AABB) regarding the proposed payment decreases for certain blood products:

> *The Panel recommends* that CMS use its 2005 payment rates as the floor for payment rates for all blood and blood products for 2006; specifically, CMS should pay the greater of 1) the simulated median as determined by 2004 data or 2) the 2005 payment median.[6]

**The Red Cross strongly urges CMS to accept *The Panel*'s recommendation and use 2005 APC payment amounts for blood products as a floor for 2006 payment amounts.**

**Recommendation 2: Update the OPPS Blood Billing Guidelines on at Least an Annual Basis**

The Red Cross truly appreciates CMS's issuance of comprehensive OPPS blood billing guidelines earlier this year. Since the guidelines were released in March 2005, the Red Cross has actively educated hospitals on the guidelines through our reimbursement email service and at reimbursement seminars throughout the country. While hospitals also are appreciative of the new guidelines, we consistently find that many providers remain confused about key aspects of blood billing.

We have received numerous inquiries from hospitals who are unclear as to whether they must follow the new blood coding requirements (involving reporting the BL modifier, as well as both the 380 and 390 revenue codes). Since these hospitals obtain their blood from the Red Cross, they pay only for blood processing and handling (rather than the blood itself) and, therefore, are not subject to these new requirements. This is true for the majority of U.S. hospitals, even for those who obtain their blood from suppliers other than the Red Cross.

---

[5] Report of *The Panel*, September 1-2, 2005, p. 5, available at: http://www.cms.hhs.gov/faca/apc/090104minutes.pdf

[6] Report of *The Panel*, August 17-18, 2005, p. 13, available at: http://www.cms.hhs.gov/faca/apc/Minutes09-14-2005.pdf

For example, the section of Transmittal 496 that outlines the new requirements begins with the following heading: "New Modifier and Billing Requirements When an OPPS Provider Purchases Blood or Blood Products from a Community Blood Bank ..."[7] Based on this language, it is understandable that a hospital who obtains blood from the Red Cross might think that they are "purchasing blood products from a community blood bank," even though they actually are paying only for processing. Upon reading the guidelines, hospitals may conclude that they must change their blood billing practices in order to comply with the new coding requirements.

Given that the new coding requirements affect only a small percentage of hospitals, we believe that it is important for CMS to clarify this issue as soon as possible. At the August 2005 meeting of *The Panel*, John Carlsen, a principal at Covance Market Access Services who conducts the Red Cross reimbursement seminars and assists Red Cross hospital customers with reimbursement issues, suggested that CMS update its OPPS blood billing guidelines on an annual basis.[8] We agree with this suggestion and encourage CMS to use its first update of the guidelines as an opportunity to clarify that the new coding requirements only apply to hospitals that pay for the blood itself. We also ask that CMS include clarification on this subject in the calendar year 2006 OPPS final rule. Additionally, the Red Cross is collaborating with others in the blood banking community to develop more comprehensive recommendations on how the blood billing guidelines could be improved and clarified; we expect to provide these recommendations to CMS in the near future.

**The Red Cross recommends that CMS update its OPPS blood billing guidelines on at least an annual basis.**

## SUMMARY OF RECOMMENDATIONS

In summary, the Red Cross praises CMS for its appreciation of the challenges hospitals have faced with inadequate reimbursement levels, as well as for issuing comprehensive blood billing guidelines this spring. We hope that these guidelines ultimately will improve the quality and accuracy of hospital claims data for blood products; however, due to the timing of the guidelines (March 2005), any improved claims data would not be available for rate-setting until the 2007 OPPS update.

In the meantime, we urge CMS to: (1) use 2005 APC payment amounts for blood products as a floor for payment in 2006, and (2) update its OPPS blood billing guidelines on at least an annual basis. The Red Cross would like to thank CMS for its considertion of these important issues.

---

[7] CMS Transmittal 486, March 4, 2005, p. 3, available at: http://www.cms.hhs.gov/manuals/pm_trans/R496CP.pdf

[8] Report of The Panel, August 17-18, 2005, p. 13, available at: http://www.cms.hhs.gov/faca/apc/Minutes09-14-2005.pdf

The Red Cross appreciates this opportunity to provide public comments on the proposed rule. If you have any further questions or require follow-up, please contact Kamenna Lee, Director, Hospital Sales and Marketing, at 202-303-5443 (phone), 202-303-0078 (fax), or leekam@usa.redcross.org (e-mail).

Sincerely,

Kamenna Lee
Director, Hospital Sales and Marketing
Biomedical Services
American Red Cross

**Submitter :** Dr. Michael Olson

**Organization :** St. Anthony Medical Center

**Category :** Pharmacist

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

I believe that the rates you are proposing are too low and will make it difficult to continue providing these services. Please reconsider better reimbursement.

Thanks, Mike Olson
Direct of Pharmacy
Crown Point, IN

**Submitter :** Ms. Deborah Walter

**Date:** 09/16/2005

**Organization :** Association of Community Cancer Centers

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1501-P-618-Attach-1.DOC

CMS-1501-P-618-Attach-2.PDF

CMS-1501-P-618-Attach-3.PDF

The premier education and advocacy organization for the oncology team

ACCC
Association of Community Cancer Centers



September 16, 2005

*BY ELECTRONIC FILING*

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the

Federal Register on July 25, 2005 (the "Proposed Rule").[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies in the most appropriate settings. Hospital outpatient departments are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. Our members also play an important role in the health care safety net. In some cases, hospital outpatient departments are the only sites available for Medicare and uninsured patients who need cancer care. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, hospital outpatient departments play an important role in the early adoption of new technologies and frequently serve patients who have recently completed participation in clinical trials.

As we consistently comment , adequate OPPS payment rates for cancer drugs[2] and the services required to prepare and administer them are critical to ensuring patient access to care. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Medicare payments for cancer drugs have been reduced significantly. When CMS introduced average sales price (ASP) based reimbursement in the physician office setting, it also implemented new, revalued codes for drug administration services, the Improved Quality of Care for Cancer Patients Undergoing Chemotherapy Demonstration Project, and transition payment of 32% in 2004 and 3% in 2005. These adjustments helped to protect Medicare beneficiaries' continued access to cancer care in physician offices. Although the MMA's reforms are likely to produce similar reductions in OPPS reimbursement for cancer drugs, CMS has not made comparable adjustments in the hospital

---

1 70 Fed. Reg. 42673 (July 25, 2005).

2 We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

outpatient setting. The combined effects of the reductions and changes in reimbursement proposed policies seem to be slowly dismantling multi-disciplinary cancer care, which is certainly not CMS's intent. We believe that it is critical to establish reimbursement rates that will ensure hospitals are appropriately reimbursed for the services they provide. We have heard from several members that the continued "hits" to the entire service line may lead to hospitals choosing to close entirely their infusion units. Indeed in the Tidewater area of Virginia, three outpatient infusion centers have closed citing perceived reductions to reimbursement as a primary reason for their decision.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2006 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Implement the proposal to reimburse most separately paid drugs at 106 percent of ASP, while monitoring the payment rates for all drugs for precipitous drops in reimbursement;
- Implement the proposal to pay separately for anti-emetics and low osmolar contrast material;
- Implement the proposal to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios and begin working with stakeholders now to develop a future rate setting methodology that accounts for all of the costs of providing radiopharmaceuticals;
- Increase the add-on payment for pharmacy handling costs to at least 8 percent of ASP, instead of the proposed 2 percent, and consider making an appropriate fixed rate add-on payment to reimburse pharmacy service costs for packaged drugs because they require a similar level of pharmacy resources to prepare;
- Postpone implementation of the proposed C-codes to report pharmacy overhead charges to allow more time to refine this proposal and examine alternate solutions;
- Revise the coding and payment policies for drug administration services to make separate payment for additional hours of infusion services and to allow hospitals to bill for more than one "initial" service code in a single day;
- Extend the cancer care quality measurement demonstration project to hospital outpatient departments;
- Issue proposed coding guidelines for evaluation and management services to help hospitals bill appropriately for cancer therapy support services;
- Continue to study the economies of providing multiple diagnostic imaging services in the same family during the same session and implement a

reduction of no more than 25 percent for these services in the meantime; and

- Reconsider the proposed rates for brachytherapy APCs.

These issues and others are described in depth below.

## I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals – NonPass-Throughs

### A. Payment for Drugs and Biologicals

ACCC generally supports CMS' proposal to reimburse most separately paid drugs at 106 percent of ASP. We believe this rate is a reasonable estimate of hospitals' average acquisition cost for many drugs, and we are hopeful that CMS' regular quarterly updates to its ASP data will allow timely adjustments to OPPS payments to reflect current market conditions. The proposed payment rate offers simplicity to the OPPS for both CMS and providers by treating almost all separately paid drugs uniformly. Paying for separately paid drugs the same way pass-throughs are reimbursed creates appropriate incentives to provide the most effective therapies, regardless of their cost and reimbursement amounts. CMS should implement this proposal for most separately paid drugs in the final rule and to make exceptions as needed to protect access to quality care. As recommended by the Advisory Panel on Ambulatory Payment Classification Groups (the "APC Panel"), CMS should monitor all drugs for precipitous drops in reimbursement that could harm patient access to needed drugs.

ACCC also commends CMS' proposal to pay separately for anti-emetics and low osmolar contrast material.[3] We agree that separate payment for anti-emetics will help ensure that Medicare's payment rules "do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[4] Separate payment for low osmolar contrast material will help to protect beneficiary access to the most appropriate therapies as well.

We also support CMS' proposal to "permit market forces to determine the appropriate payment" by applying the ASP methodology to biologicals that were subject to an "equitable adjustment" in 2005.[5] We recommend that CMS implement this proposal in the final rule.

---

3 70 Fed. Reg. at 42723, 42727.
4 70 Fed. Reg. at 42723.
5 70 Fed. Reg. at 42727.

### B. Payment for Radiopharmaceuticals

ACCC supports CMS' proposal to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios.[6] We believe this is an appropriate short-term payment methodology, but we remain concerned about the future payment methodology for radiopharmaceuticals. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique bundle of services, such as compounding, dosimetic and therapeutic infusions, and scanning of the patient to assess biodistribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed under the OPPS.

ACCC is concerned that if the OPPS does not appropriately reimburse for all of the costs of providing radiopharmaceuticals, hospitals will not be able to continue to provide these advanced treatments. We recommend that CMS finalize its proposed payment methodology for radiopharmaceuticals in 2006. To ensure that hospitals can provide the most appropriate radiopharmaceuticals for their patients, we urge CMS to begin working with stakeholders now to develop a future rate-setting methodology that accounts for all of the costs of providing these treatments. We recommend that CMS explore the possibility of treating radiotherapies such as such as BEXXAR® and Zevalin® differently from traditional radiopharmaceuticals in order to preserve patient access to them.

### C. Payment for Pharmacy Handling Costs

Although ACCC generally supports the proposal to use 106% of ASP as a proxy for hospital acquisition costs, we are greatly concerned that the additional 2% CMS has proposed for pharmacy service costs will not be adequate to support hospitals' ability to provide advanced cancer drugs. We also believe that further studies and additional guidance are needed before hospitals can begin to use the proposed C-codes to report their pharmacy overhead charges accurately and consistently. Unless high quality data are collected soon, CMS will not have the information it needs to set more appropriate rates in the future.

#### 1. Proposed Payment Rate for Pharmacy Handling Costs

The advanced drugs we use to help our patients fight cancer require careful handling by specially trained personnel. When it enacted the MMA, Congress recognized that an acquisition cost-based reimbursement methodology might not account for these pharmacy service costs. To determine whether

---

[6] 70 Fed. Reg. at 42727.

OPPS rates should be adjusted to reflect these costs, Congress instructed the Medicare Payment Advisory Commission (MedPAC) to study pharmacy service and handling costs. MedPAC's report, released in June, concluded that these costs are significant and that an adjustment is warranted.

MedPAC cited studies that found pharmacy service overhead costs to make up 26 to 33 percent of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs.[7] Most of the overhead costs reflect ancillary supplies (gowns, booties, masks) and salaries and benefits of pharmacists and technicians. These personnel not only prepare the drugs, they also ensure that patients receive the appropriate dose of a drug, in the correct sequence, and through the safest administration method. This sequence of activities is commonly referred to as "safety through redundancy." Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of drug, such as labelling, recording, and tracking mixed drugs for safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions.

The remaining pharmacy service costs include contract negotiations, building and information systems maintenance and upgrades, transportation of drugs within the hospital, and disposal of unused products (that typically involve the housekeeping department) to comply with Environmental Protection Agency (EPA) and National Institute for Occupational Safety and Health (NIOSH) regulations. Accordingly, costs for these items and services are affected by regulatory and accreditation standards and can increase dramatically when these standards change. For example, many hospitals currently bear the costs of renovating their facilities to comply with the new sterile compounding standards of the United States Pharmacopeia Chapter 797.

CMS proposes to pay an additional 2 percent of ASP for separately paid drugs to cover these costs.[8] This proposed add-on equals only 1.9 percent of a drug's acquisition cost of 106% of ASP before any adjustments for budget neutrality. This is drastically less than the 35 to 50 percent of acquisition cost that the studies cited by MedPAC attribute to overhead costs.[9] Indeed, it is far

---

7 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

8 70 Fed. Reg. at 42730.

9 If pharmacy service costs equal 26 percent of total hospital outpatient pharmacy costs, then the acquisition cost of drugs equals 74 percent of the total costs. Pharmacy service costs therefore equal 35 percent (26/74) of acquisition cost.

less than the 30 percent of acquisition cost that our own ACCC study found was attributed to pharmacy service and handling costs when we surveyed our pharmacy members. A more detailed analysis can be found in Appendix 1.

ACCC agrees with the APC Panel's conclusion that 2 percent of ASP is not adequate, yet we also understand it would be difficult for the agency to set pharmacy service payment rates in the range of 30 to 50 percent of ASP because of the ramifications this would have for other services paid under the OPPS. In an attempt to reach a reasonable compromise we used the hospital outpatient claims data to examine the percentage add-on to ASP that would be necessary to maintain aggregate payments in 2006 at 95 and 100 percent of the 2005 level. ACCC believes that this comparison is appropriate because prior to the introduction of acquisition cost-based reimbursement, the OPPS rates for drugs included pharmacy handling costs.[10] Accordingly, the combined payments in 2006 for acquisition cost and pharmacy handling services should be comparable to the 2005 payments that were intended to include both acquisition cost and pharmacy services.

As Table 1, below shows [see Appendix 2 for additional details], we found that a 19.7 percent add-on to ASP is necessary to maintain payments for chemotherapy or supportive care drugs at 2005 levels (or a 13.7 percent add-on to maintain payments at 95 percent of 2005 levels). For all other drugs except radiopharmaceuticals, a 13.3 percent add-on is necessary (or a 7.6 percent add-on to maintain at 95 percent of 2005 levels). Based upon this analysis, ACCC urges CMS to implement a pharmacy service and handling add-on of at least 8 percent of ASP, in addition to the acquisition cost payment of ASP plus 6 percent.

---

10 MedPAC notes in its June 2005 report that "historically, Medicare payments were sufficient to cover both [acquisition costs and handling costs]," but "moving to a payment system based on acquisition cost will no longer compensate hospitals for handling costs as part of the payment for the drug itself." Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139, 140.

**Table 1: ACCC Analysis of Percent Add-on Needed to Reflect Pharmacy Service and Handling Costs**

| Drugs and Biologicals | Payment Totals (in millions $) | | | ASP Add-On Needed to Equal 95% of 2006 Payments | ASP Add-On Needed to Equal 100% of 2006 Payments |
|---|---|---|---|---|---|
| | 2005 | 2006 [NPRM] ASP+8% | 2006 [NPRM] ASP +0% | | |
| 130 drugs identified as chemotherapy or supportive care (excluding drugs proposed for packaging and including adjustment of payments for branded drugs) | $1,357 | $1,224 | $1,134 | 13.7% | 19.7% |
| All drugs paid under the OPPS (excluding drugs proposed for packaging and including adjustment of payments for branded drugs) | $1,693 | $1,613 | $1,494 | 7.6% | 13.3% |

Increasing the add-on percentage from 2 percent to 8 percent would increase spending about $90 million before budget neutrality adjustments, according to our own analysis. This increase equals 0.33% of the total OPPS budget for 2006. The required budget neutrality adjustment would be a reduction of less than 0.4 percent. In contrast, the budget neutrality adjustment in the proposed rule was an increase of about 0.38 percent.[11] For comparison, budget neutrality adjustments in prior years were reductions of 1.53 percent in 2005,[12] 1.84 percent in 2004,[13] and 3.1 percent in 2003.[14] We believe this approach is consistent with the agency's past practice of dampening and is an appropriate interim measure until data are collected to implement a better long term solution. Most important, an add-on of at least 8 percent is imperative to protect beneficiary access to drug therapy in the OPPS, and we urge CMS to implement this proposal.

### 2. Application of the Add-On Payment to All OPPS Drugs

ACCC also supports the APC Panel's recommendation to make the add-on payment for all drugs, regardless of whether they are packaged or separately paid under the OPPS. In its report, MedPAC correctly noted that handling costs

---

11 70 Fed. Reg. 50680 (Aug. 26, 2005).
12 69 Fed. Reg. 65681, 65770 (Nov. 15, 2004).
13 68 Fed. Reg. 63398, 63421 (Nov. 7, 2003).
14 67 Fed. Reg. 66718, 66750 (Nov. 1, 2002).

are not necessarily proportional to drug acquisition cost.[15] Although a drug's acquisition cost may be low enough to be packaged under the OPPS, the drug may require significant effort to prepare. In other words, the drug's handling costs probably are not reflected adequately in the APC in which it is packaged. To illustrate this point, for the treatment of colon and rectal cancer as a single agent (with leucovorin rescue) a physician may use 5-FU which costs $1.41 for 500 mg. The drug is prepared by pharmacy technician by drawing up two vials into a D5W solution, then labeled and verified for the correct dosage by a pharmacist before being administered to the patient. This procedure and protocol are no different than using a therapeutically equivalent regimen, IROX (combination therapy of irinotecan HCI injection and oxaliplatin) at a cost of $129.08 per 20 mg and $84.06 per 5 mg, respectively. A similar level of pharmacy resources are involved because the irinotecan HCI injection is drawn up into D5W solution while the oxaliplatin requires reconstitution. Yet we would receive the pharmacy handling cost payment for irinotecan and oxaliplatin because they are not packaged, but would not receive the payment for 5-FU. We urge CMS to reimburse hospitals for the costs of preparing all drugs by making an appropriate fixed rate add-on payment to reimburse pharmacy service costs for packaged drugs in addition to the add-on of at least 8 percent of ASP for separately paid therapies.

Additional examples of treatment regimens that use similar pharmacy resources but would be treated differently under CMS' proposal are the COMLA and CHOP-R treatments for Non-Hodgkins lymphoma. The COMLA combination regimen consists of cyclophosphamide ($19.03 for 1000 mg), vincristine ($5.93 for 2 mg), methotrexate ($5.33 for 100mg), cytarabine ($1.65 for 100mg), and oral leucovorin. The cyclophosphamide and cytarabine must be reconstituted by the pharmacy technician and added into a D5W solution like the methotrexate. The pharmacy technician also must draw the vincristine up into a syringe. The pharmacist must label each drug is and verify the correct dosage before the drugs are administered to the patient. This procedure and protocol are no different than using a therapeutically equivalent regimen, CHOP-R. This regimen consists of cyclophosphamide ($19.03 for1000 mg), doxorubicin ($53.93 for 100 mg), vincristine ($5.93 for 2mg), rituximab ($2239.85 for 500 mg), and oral prednisone. A similar level of pharmacy resources are involved for the CHOP-R combination regimen because both regimens must be prepared by the pharmacy technician as intravenous infusions, labeled and verified. However, hospitals would only receive the pharmacy handling cost payment for CHOP-R because the drug cost is above the $50.00 threshold. They

---

15 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 142.

would not receive the pharmacy handling cost payment for COMLA because the drugs are packaged with the procedure fee.

We recommend that CMS make an add-on payment of at least $14.80 per dose of packaged drug administered. We basis this recommendation on an analysis of the amount of pharmacist and pharmacy technician time, plus indirect overhead costs, associated with preparing each dose. We estimate that a single dose would require, on average, 10 minutes of technician time and 10 minutes of pharmacist time to prepare, including performance of all of the necessary quality assurance tasks. Using a median hourly wage of $57.92 ($40.82[16] plus benefit costs of 41.9%[17]) for pharmacists and $16.13 ($11.37[18] plus benefit costs of 41.9%) for pharmacy technicians, adjusted by an additional 20% for indirect overhead costs and supplies, we estimate the handling costs per dose to be $14.80. We recommend that CMS make this additional payment for each dose of each drug administered. The agency should consider establishing a new G-codes for pharmacy handling services associated with packaged drugs for this purpose.

### 3. Proposed Codes for Pharmacy Service Costs

The APC Panel also recommended that CMS delay implementation of the proposed codes for drugs handling cost categories until January 2007 to allow more time to study this issue. ACCC concurs with this recommendation. While we appreciate MedPAC and CMS' thoughtful approach to this issue, we are concerned that hospitals will not be able to use the C-codes effectively in 2006. As MedPAC observed, most hospitals do not currently charge for their handling costs, and no systematic, consensus based approach exists for measuring these costs.[19] We expect that developing charges will be a difficult undertaking, particularly for hospitals that currently allocate some of their pharmacy costs, such as temporary technician staffing and information technology, to other cost centers. Many hospitals may be reluctant to make this effort if the C-codes are not linked to immediate reimbursement. Rather than implementing the C-codes in 2006 without clear guidance on their use, a consistent method of reporting charges, or an incentive to develop charges, we recommend that CMS continue to refine this proposal and study alternate methods of reimbursing hospitals for

---

[16] U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages, May 2004, Pharmacists, available at http://www.bls.gov/oes/current/oes291051.htm.
[17] U.S. Department of Labor, Bureau of Labor Statistics, Private Industry, Health Care and Social Assistance Workers, by Industry and Occupational Group, March 2005, Hospitals: Management, Professional, and Related, available at http://www.bls.gov/news.release/ecec.t14.htm.
[18] U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages, May 2004, Pharmacy Technicians, available at http://www.bls.gov/oes/current/oes292052.htm
[19] Id. at 143.

pharmacy overhead costs. In the meantime, we urge CMS to make adequate add-on payments as we discussed above.

## III. Drug Administration

ACCC supports CMS' proposal to begin using the new drug administration CPT® codes in the OPPS in 2006. We believe the new codes, describing drug administration services in greater detail than the old codes, will help CMS collect the data it needs to set more appropriate payment rates in the future. At present, however, we are concerned that the proposed rates for these services will not provide adequate reimbursement for hospitals' costs of providing drug therapies, particularly for the large number of our patients who receive multiple infusions in a single visit or whose infusions take more than one hour to administer. Because physicians tend to send patients requiring longer and more complex infusions to the OPPS, these are precisely the cases for which reimbursement should be adequate to preserve access to care.

Our review of the proposed crosswalk and the instructions issued to physicians regarding the correct use of the new codes has identified a major conflict between the coding guidelines for the use of the new codes by physicians and Medicare's coding and payment policies for drug administration under the OPPS. CMS proposes to map the new drug administration CPT® codes to existing APCs and to package payment for all codes that describe additional hours, subsequent infusions, or concurrent infusions into the code for the initial service.[20] This proposal, combined with the CPT's instructions to report only one "initial" service code when administering multiple infusions or injections, means that hospitals will be paid only for the first hour of the first infusion service provided. All other services provided on the same day, including administration of other drugs or hydration, would not be reimbursed under the OPPS, although the same services would be paid when provided in a physician's office.

We will use a typical cancer patient to illustrate the problem. Before certain types of chemotherapy are administered, it often is necessary to hydrate the patient. As the table below shows, under current 2005 coding guidelines and CMS payment policy, a hospital would report codes 90780 and 96410. These codes are assigned to APCs 0120 and 0117, respectively, and a full APC payment is made for each service. Under the physician CPT coding guidelines for the new codes, only one "initial" code could be billed. Thus, the correct coding of an hour of hydration therapy followed by an hour of chemotherapy by infusion would be the new CPT codes that will correspond to codes G0359 *Chemotherapy Administration, Intravenous Infusion Technique; up to one hour* and G0346

---

[20] 70 Fed. Reg. at 42738.

*Intravenous Infusion, Hydration; each additional hour.* As shown by the table below, the new CPT code corresponding to code G0346 is a packaged service, and no separate payment will be made.

| 2005 CPT Code | 2005 HCPCS Code | Description | CY 2006 Proposed Status Indicator | APC |
|---|---|---|---|---|
| 90780 | G0345 | Intravenous Infusion, Hydration; Initial, up to one hour | S | 0120 |
| 90781 | G0346 | Intravenous Infusion, Hydration; each additional hour, up to eight (8) hours | N | --- |
| 96410 | G0359 | Chemotherapy Administration, Intravenous Infusion Technique; up to one hour, single or initial substance/drug | S | 0117 |
| 96412 | G0360 | Chemotherapy Administration, Intravenous Infusion Technique; Each additional hour, one to eight (8) hours | N | --- |

Thus, if adopted for use under OPPS, the new coding guidelines would lead to reduced payments that would be inconsistent with existing and proposed OPPS payment policy. ACCC is deeply concerned that patient access to cancer drugs and biologicals in hospital outpatient departments will be harmed drastically if CMS implements this proposal. It is imperative for CMS to issue instructions to hospitals and fiscal intermediaries to clarify that unlike in a physician office, more than one "initial" code may be used for reporting drug administration services in the hospital outpatient setting.

Additionally, we urge the agency to make separate payment additional hours of infusion services. Hospital outpatient departments frequently treat patients who require infusions administered over several hours. For example, one ACCC member indicated that in June of this year, her hospital treated 177 patients who required multiple hours of chemotherapy infusions. Due to the differences in reimbursement for drug administration services in the hospital outpatient department compared to physician offices, the hospital was reimbursed almost $35,000, or $200 per patient, less than a physician office would have been paid for treating the same patients. Similarly, another member indicated that they have been treating a patient who failed first line treatment for acute promyelocytic leukemia and is now undergoing second line treatment. Arsenic trioxide, an orphan drug, is the best hope for patients with this rare

form of leukemia who have not responded to other treatment. Because this drug must be administered seven days a week for six months, most patients with this condition must seek treatment in hospitals. However, under the OPPS, hospitals would be reimbursed for only half the time involved in administering the drug, resulting in payment for the course of treatment that is $2000 less than what a physician office would receive for the same regimen. If inadequate Medicare reimbursement leaves hospitals unable to provide these services, some patients may have nowhere else to go for care. Patients who require infusions administered over periods of 8 hours, seven days a week, or in other situations that are outside normal physician office hours depend on hospital outpatient departments to provide their critical cancer treatments.

We understand that CMS is collecting charge and cost data for all the CPT codes to determine an appropriate payment rate for all the services, including those that are currently packaged. It appears that the earliest CMS would implement separate payments for these services would be January 2007, however. Our review of 2004 OPPS claims data identified 4,069 claims for 90781 *IV infusion, add'l hour* and 719 claims for 96412 *Chemotherapy infusion, add'l hour* even though these codes are not recognized for payment. The average costs for the two services were $70.28 and $77.71, respectively. In addition to this data, there is partial year data from 2005 available to CMS for use in calculating payment rates for these packaged codes. We ask CMS to use this data to establish separate payments so that more equitable payments for prolonged drug administration services can be established effective January 1, 2006.

Finally, we ask CMS to provide clear instructions on the appropriate use of the new codes in hospital outpatient departments. The new codes use a fundamentally different structure and vocabulary from the codes currently used by hospitals, and we anticipate that hospital staff will need guidance on how to use them correctly. We recommend that CMS issue this guidance in the final rule and in Medlearn Matters articles. We also ask CMS to issue clear instructions to report administration of substances such as monoclonal antibody agents and other biological response modifiers under the chemotherapy codes. This instruction was provided in the 2005 final physician fee schedule rule and a subsequent Medlearn Matters article, but was not included in the OPPS proposed rule.

## IV. Demonstration Of Improved Quality Of Care For Cancer Patients Undergoing Chemotherapy

In 2005, CMS began a demonstration project to measure outcomes among patients receiving chemotherapy. This demonstration project measured patients' levels of fatigue, pain, and nausea during chemotherapy

administration. Physicians enrolled by reporting specific codes and received payment for each code reported. The demonstration not only helped to measure the quality of care provided to Medicare beneficiaries, it also helped to protect access to chemotherapy by easing the transition to ASP-based reimbursement and new payment rates for drug administration services. CMS recently announced its intention to "engage all stakeholders on the merits of the program and the opportunities to better capture data on the clinical care of patients with cancer, and improve the provision of that care."[21] Because hospitals share the same quality of care concerns and are similarly affected by Medicare's payment reforms, we urge CMS to expand the demonstration project to cancer care provided in hospital outpatient departments. ACCC looks forward to working with CMS to develop appropriate measurements, and we will discuss our recommendations for the next phase of this demonstration in greater detail in our comments on the proposed physician fee schedule rule.

## V. E/M Services

We also are concerned that CMS has not yet issued coding guidelines for evaluation and management services provided during clinic visits. These guidelines would help hospitals bill for cancer therapy support services that help patients achieve the full benefits or their drug regimens by managing their course of treatment, maintaining their nutritional status, providing psychological and emotional counseling, and educating patients and their families about their illness, treatment options, and possible side effects. Cancer therapy support services include:

- Social services - planning for home care, hospice and long-term care, community agency referrals, and referrals for transportation assistance;
- Nutrition services - evaluation of the patient's nutritional status, the provision of information about diet and cancer, and the development of nutrition plans to meet the individual patient's needs;
- Patient and family education - educating newly diagnosed patients and their families about their cancer, treatment options, support resources, self-care techniques, new prescribed treatments, and coping with and managing treatment side effects; and
- Psychosocial support - services to address the psychological and emotional aspects of cancer and cancer treatment.

Cancer therapy support services are indispensable components of quality cancer care, yet many hospitals are not being reimbursed for them because they

---

[21] CMS Fact Sheet: Demonstration Of Improved Quality Of Care For Cancer Patients Undergoing Chemotherapy, Aug. 1, 2005, http://www.cms.hhs.gov/media/press/release.asp?Counter=1525.

do not know how to bill for them. Instructions in the Medicare Benefit Policy Manual state that therapeutic services provided by hospitals on an outpatient basis can be covered as "incident to" physicians' services if they are an "integral, although incidental, part of the physician's service in the course of diagnosis or treatment of an illness or injury."[22] We believe these services are covered under the OPPS, but hospitals often do not know when or how to bill for them. Except for psychosocial support services (CPT codes 90804-90857), which are paid under APCs 322-325, these services are most likely represented by E/M codes.

We understand that CMS has been considering recommendations from the AHA/AHIMA expert panel for a national set of coding guidelines for hospital clinic visits, including visits for cancer care support services. We are disappointed that CMS has not proposed guidelines, but instead merely instructs us to sign up for a public listserve through which we will be notified of the guidelines when they are proposed at last.[23] CMS anticipates a delay of at least 6 to 12 months from the proposal of guidelines to their implementation to allow ample time for comment. We ask CMS to issue the proposed guidelines as soon as possible so that we can begin the public comment process and implement new codes and guidelines next year.

## VI. Multiple Diagnostic Imaging Procedures

ACCC is dismayed by CMS' proposal to reduce payment by 50 percent for second and subsequent imaging procedures within the same family when performed in the same session.[24] Imaging services are critical to cancer care, both for the initial diagnosis and for assessing the effectiveness of treatment. ACCC is greatly concerned that this payment cut will harm patient access to these important services. Reducing payment for multiple procedures this dramatically could discourage hospitals from investing in new technologies. It also could incentivize hospitals to schedule imaging services over several days, increasing the patient's inconvenience and potential exposure to contrast media. Reduced payment also could lead to increased use of invasive diagnostic techniques that put the patient at greater risk for complications and ultimately may cost the patient and Medicare more.

ACCC asks CMS to reconsider this proposal. Although we believe there may be some economies of scale when multiple imaging procedures are performed during the same session, we believe they are minimal and do not come close to warranting a 50 percent reduction to the technical component. Contrary to CMS' assumptions, there is no standard economy of scale when

---

22 Medicare Benefit Policy Manual (CMS Pub. 100-02), ch.6, § 20.4.1.
23 70 Fed. Reg. at 42740.
24 70 Fed. Reg. at 42751.

multiple procedures are performed. In fact, on a per service basis, the amounts of technologist time to position the patient and perform the imaging and contrast material administered to the patient often are not reduced when multiple services are performed in a single session. The equipment costs, including depreciation and maintenance, remain the same per image regardless of the number of procedures performed during a visit. We question CMS' conclusion that a 50 percent reduction is justified, and we urge the agency to conduct further studies to determine the actual savings applicable to performing multiple imaging services in a single session. CMS should consider the APC Panel's recommendation for CMS to work with the American College of Radiology to define which procedures should be subject to the reduction and the size of any reduction. As a temporary measure while these studies are being conducted, we recommend that CMS implement a payment reduction of no more than 25 percent for the second and subsequent imaging services within the same family of services performed during the same session.

## VII. Brachytherapy

ACCC is concerned that CMS' proposal to reduce payments for the brachytherapy APCs (312, 313, and 651). Lowered reimbursement for these advanced cancer treatments could jeopardize hospitals' ability to offer brachytherapy as a treatment option. To protect Medicare beneficiaries' access to the most appropriate cancer treatments, we recommend that CMS reconsider its proposed rates for these APCs. Specifically, we recommend that CMS base its rates on correctly coded claims only, continue to educate hospitals on the importance of accurately coding brachytherapy claims, and apply a dampening adjustment to stabilize the rates of all device-related APCs.

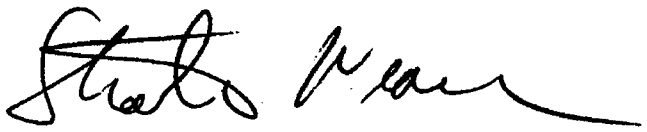
## VIII. Conclusion

ACCC urges CMS to protect cancer patients' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPPS. Toward this end, we believe it is imperative for CMS to increase the add-on payment for pharmacy handling costs to at least 8 percent of ASP and make an appropriate fixed rate add-on payment to reimburse pharmacy service costs for packaged drugs. In addition, it is critical that CMS revise the coding and payment policies for drug administration services to make separate payment for additional hours of infusion services and to allow hospitals to bill for more than one "initial" service code in a single day. CMS should work with ACCC and other stakeholders to develop and implement a quality improvement demonstration project for cancer care provided in hospital outpatient departments, similar to the demonstration project implemented in physician offices in 2005. We also urge CMS to rethink its proposal with respect

to multiple diagnostic imaging services in the same family performed during the same session. CMS should continue to study the economies of providing multiple diagnostic imaging services and implement a reduction of no more than 25 percent for these services in the meantime. Moreover, we urge CMS to begin working with stakeholders now to develop a future rate setting methodology that accounts for all of the costs of providing radiopharmaceuticals, postpone implementation of the proposed C-codes for pharmacy overhead charges and study this issue in greater depth, issue proposed coding guidelines for evaluation and management services to help hospitals bill appropriately for cancer therapy support services, and reconsider the proposed rates for the brachytherapy APCs.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact our staff person, Deborah Walter, at (301) 984-5067, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

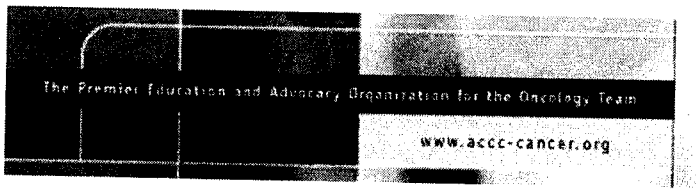


E. Strode Weaver, FACHE, MBA, MHSA
President, Association of Community Cancer Centers

Attachments

#618-2

Appendix 1: ACCC Survey Findings of 2005 Hospital Outpatient Pharmacy Overhead and Handling Cost Survey

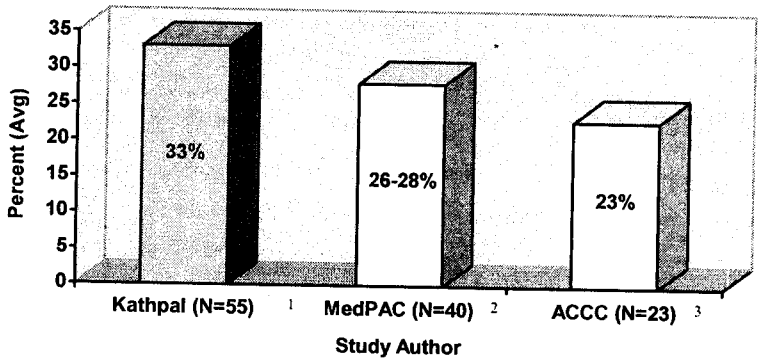



ACCC
Association of Community Cancer Centers

# ACCC Survey Findings of 2005 Hospital Outpatient Pharmacy Overhead and Handling Cost Survey

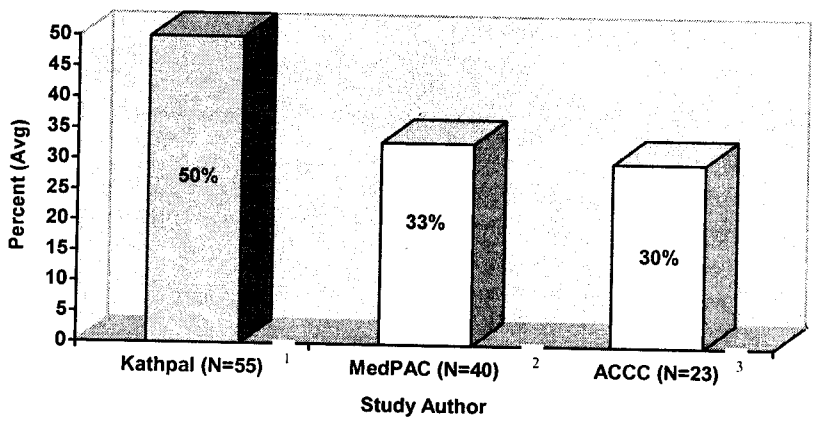
*Three recent independent reports—including a report conducted by an independent federal commission created by Congress-similarly concluded that hospital outpatient department (HOPD) pharmacy overhead costs account for approximately one quarter to one-third of total HOPD direct and indirect costs.*

**HOPD Pharmacy Overhead Costs as Percentage of Total HOPD Direct Costs, by Study Author**




*The three recent independent reports also similarly concluded that hospital outpatient department (HOPD) pharmacy overhead costs account for approximately one-third to one half of total HOPD drug acquisition costs.*

**HOPD Pharmacy Overhead Costs as Percentage of HOPD Drug Acquisition Costs, by Study Author**




[1] Myers and Stauffer LC, *High Cost Drugs Under the Outpatient Prospective Payment System* (Draft Report: Health Care Financing Administration, September 8, 1999; analysis of 1996 Medicare hospital cost report data

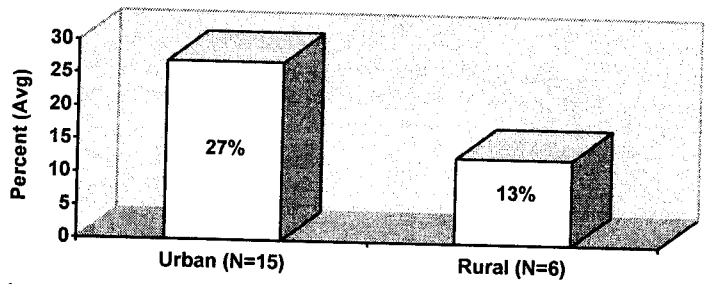
[2] Medicare Payment Advisory Commission, *Report to Congress: Issues in a Modernized Medicare Program*, June 2005; MedPAC analysis of cost data for ~40 hospitals in Maryland from 2001 to 2003

[3] ACCC analysis of 2004 pharmacy cost data from 23 HOPDs; total does not add up to 23 because not all respondents provided demographic information. Outlier data from 4 respondents excluded from the results and not reported.

# ACCC Survey Findings of 2005 Hospital Outpatient Pharmacy Overhead and Handling Cost Survey [continued]

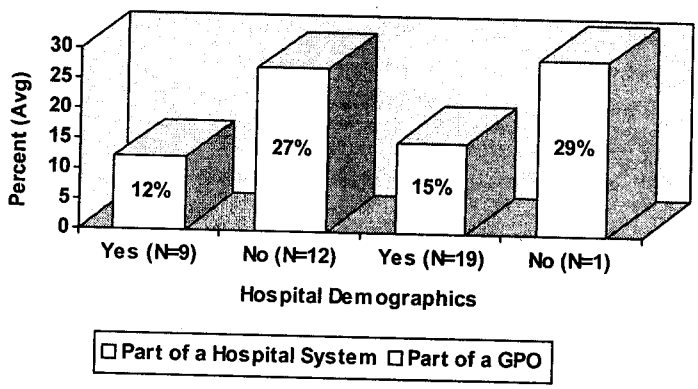
*Compared to rural areas, ACCC survey respondents working in HOPDs located in urban areas reported considerably higher pharmacy overhead costs as a percentage of total HOPD drug costs (13% vs. 27%, respectively). Survey data suggest that higher average costs per square foot/rent as well as salary and benefits likely account for this difference.*

**ACCC Survey of HOPD Pharmacy Overhead Costs as Percentage of Total HOPD Direct Costs, by Location** [4]



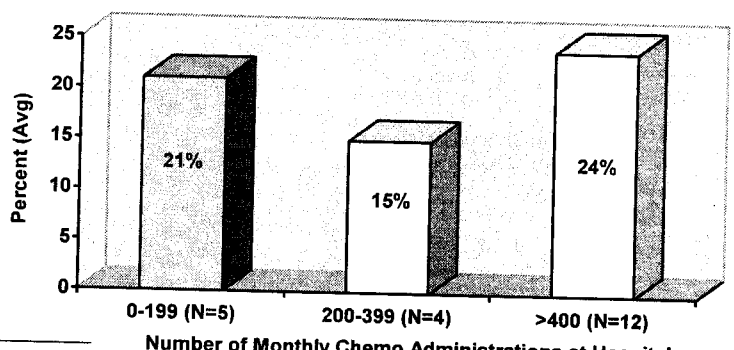

*ACCC survey respondents who are not part of a hospital system or group purchasing organization (GPO) reported higher pharmacy overhead costs as a percentage of total HOPD drug costs compared to those who are part of a larger or integrated hospital system (27% vs. 12%, respectively) or GPO (29% vs. 17%, respectively). Presumably, this difference may reflect pricing discounts that are tied to greater volume drug purchasing or market share.*

**ACCC Survey of HOPD Pharmacy Overhead Costs as Percentage of Total HOPD Direct Costs, by Category** [5]




*ACCC survey respondents who provide the largest number of monthly chemotherapy administrations (i.e., over 400) tend to have the highest pharmacy overhead costs as a percentage of total HOPD drug costs, compared to those with lower volumes [(i.e., less than 200 and between 200 and 400) 25%, 21%, and 15%, respectively].*

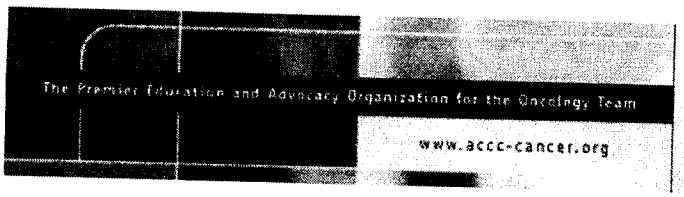
**ACCC Survey of HOPD Pharmacy Overhead Costs as Percentage of Total HOPD Direct Costs, by Volume** [6]

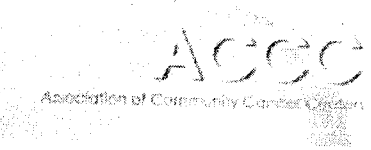



4.5.6: ACCC analysis of 2004 pharmacy cost data from 23 HOPDs; total does not add up to 23 because not all respondents provided demographic information/ Outlier data from 4 respondents excluded from the results and not reported.

#618-3

Appendix 2: ACCC Analysis of Percent Add-on Needed to Reflect Pharmacy Service and Handling Costs




# 2006 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT PROPOSED RULE: IMPACT ANALYSIS ON DRUG PAYMENTS

- **Table 1** shows the impact of the proposed rule on drug, biological, and radiopharmaceutical payments in the hospital outpatient prospective payment system (HOPPS).

## Table 1: Comparison of Total HOPPS Payments for all Drugs, Biologicals and Radiopharmaceuticals

| Drugs and Biologicals | Payment Totals (in millions $)[1] | | | Difference (in millions $) | |
|---|---|---|---|---|---|
| | 2004 | 2005 | 2006 [NPRM][2] | 2006 vs 2005 | 2006 vs 2004 |
| 130 drugs identified as chemotherapy or supportive care | $1,429 | $1,375 | $1,224 | -$150 | -$204 |
| All drugs paid under the OPPS | $1,965 | $1,886 | $1,613 | -$272 | -$351 |

- **Table 2** shows the impact of the proposed rule on drug and biological payments in the HOPPS, excluding radiopharmaceuticals.[2]

  - For 130 chemotherapy or cancer supportive care drugs and biologicals, payments would decrease by approximately $141 million in 2006 under the proposed rule.

  - When all drugs and biologicals [excluding radiopharmaceuticals] paid under the HOPPS are considered, the aggregate payment reduction would fall to $101 million because payment rates increase for many non-cancer drugs.

## Table 2: Comparison of Total HOPPS Payments for all Drugs and Biologicals, Excluding Radiopharmaceuticals

| Drugs and Biologicals | Payment Totals (in millions $)[1] | | Difference (in millions $) |
|---|---|---|---|
| | 2005 | 2006 [NPRM] | 2006 vs 2005 |
| 130 drugs identified as chemotherapy or supportive care (excluding radiopharmaceuticals) | $1,365 | $1,224 | -$141[3] |
| All drugs paid under the OPPS, (excluding radiopharmaceuticals) | $1,714 | $1,613 | -$101 |

[1] ACCC analysis based on 2004 hospital outpatient claims utilization file from the Centers for Medicare and Medicaid Services.

[2] Radiopharmaceuticals must be excluded from the comparison because they will be paid on a pass-through basis in 2006. Thus, no payment rate is shown for these items for 2006, but their payment will not be $0.

[3] Considering the $141 million net reduction for the 161 cancer drugs, about $3 million is due to elimination of the extra payments for brand drugs in 2006 and about $5 million derives from drugs that will be packaged in 2006.

## 2006 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT PROPOSED RULE: IMPACT ANALYSIS ON DRUG PAYMENTS [continued]

- **Table 3** shows the percentage add-on to the ASP rate that would be needed to maintain aggregate payments in 2006 at 95% or 100% of the 2005 level. Note that a higher percentage add-on (about 20%) is needed for drugs used in cancer care than would be required for all drugs paid under the OPPS (about 13%).

**Table 3: 2006 Add On Adjustment Needed to Compensate Hospital Outpatient Departments for Pharmacy Overhead and Handling Costs**

| Drugs and Biologicals | Payment Totals (in millions $)[1] | | | ASP Add-On Needed to Equal 95% of 2005 Payments | ASP Add-On Needed to Equal 100% of 2005 Payments |
|---|---|---|---|---|---|
| | 2005 | 2006 [NPRM] ASP+8% | 2006 [NPRM] ASP +0% | | |
| 130 drugs identified as chemotherapy or supportive care (excluding drugs proposed for packaging and including adjustment of payments for branded drugs) | $1,357 | $1,224 | $1,134 | 13.7% | 19.7% |
| All drugs paid under the OPPS (excluding drugs proposed for packaging and including adjustment of payments for branded drugs) | $1,693 | $1,613 | $1,494 | 7.6% | 13.3% |

- A total payment of ASP + 14% would provide an *allowance of 8% for pharmacy handling and overhead expenses in addition to ASP + 6% to cover the drug acquisition cost.*
  - ❖ Although substantially more adequate than the 2% add-on recommended in the proposed rule, an 8% add-on is significantly less than the 20-30% or more pharmacy cost found in the MedPAC and ACCC surveys.

- Increasing the pharmacy add-on percentage from 2% to 8% would increase spending about $90 million before budget neutrality.
  - ❖ The required budget neutrality adjustment would be a reduction of less than 0.4%. In contrast, the budget neutrality adjustment in the proposed rule was an *increase* of about 0.38 percent.
  - ❖ For comparison, the budget neutrality adjustments in prior years were reductions of 1.53 percent in 2005, 1.84 percent in 2004 and 3.1 percent in 2003.

[1] ACCC analysis of 2004 hospital outpatient claims file from the Centers for Medicare and Medicaid Services.

**Submitter :** Ms. Autumn Farmer

**Date:** 09/16/2005

**Organization :** Mercy Health Partners Southwest Ohio

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am commenting on behalf of Mercy Health Partners, a five acute care hospital system in Cincinnati, Ohio. Thank you in advance for the opportunity to comment on the proposed changes to the Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates.

"Non-Pass Throughs"
Proposed Criteria for Packaging Payment for Drugs, Biologicals and Radiopharmaceuticlas-
We agree with the proposed continuation of the existing policy to pay separately for drugs, biologicals, and radiopharmaceuticals whose cost per day exceeds $50. We also applaud your effort to improve the methodology used to estimate the cost per day for drugs and believe that the proposed changes will allow for more accurate packaging of those items with a mean cost less than $50 per day.

We respectfully request that CMS reconsider the proposal to pay for Hospital drug and biological overhead cost based on 2 percent of ASP. The June MedPac report on Hospital Outpaient Department Pharmacy handling costs sited that overhead comprised 26% to 28% of the total pharmacy direct costs. We Support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.
Futhermore, we propose that CMS re-evaluate the implementation of the Drug Handling Category C-codes for CY 2006. With the advent of electronic dispensing cabinets and bar-code scanning technology to promote patient safety, a large percent of pharmacy charge capture happens outside of the pharmacy department. Current technology does not allow for the bundling of charges in hospital clinical pharmacy systems. Therefore, it will be relatively impossible to effectively implement the charging of these new codes without manually applying them during claims processing or instituting new technology, either of which would increase hosptial cost. We are concerned that many hospitals will not report these codes, providing poor data from which to establish reimbursement.

We would also like to request that CMS consider statutorily exclude IVIG (Q9941-Q9944) from ASP reimbursement methology and continue to reimburse in CY 2006 based on 2005 current APC rates. The country is currently experiencing shortages of this drug, and our hospital system has seen the price increase as much as 45% over the last quarter alone. Reimbursement based on ASP from two quarters back will not sufficently cover the cost of this drug and may limit access of this tratment to beneficiaries.

Thank you for the opportunity to comment on this proposed rule.
Sincerely,
Autumn Farmer
Pharmacy Revenue Management
Mercy Health Partners

**Submitter :** Mrs. Terri Charles

**Date:** 09/16/2005

**Organization :** parent of CI user

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

GENERAL

My daughter just had a cochlear implant and the cost to the hospital, including the device was near 60,000$. Our insurrance company BCBS reimbursed them for 33,000$, which is significantly more than you are proposing to reimburse or even reimburse now.

I stronly disagree with your reimbursement reduction for two reasons. Number 1 it is unfair to the hospitals which either have to eat the cost (and balance the books by charging someone else more) or stop doing implants. Number 2 is that many private insurrance companies tie their reimbursement rates to the medicare rates and may use this as a justification to reduce their rates as well.

With medical costs rising all the time, I would hope you would turn to reliable, industry-wide surveys of costs to determine reimbursement. I do not see how an accurate survey could possibly lead to the decision to reduce rates.

Cochlear implants are a medical miracle. 20 years ago my daughter would be deaf, in a deaf school having her hands slapped for signing. Today she is mainstreamed in her local middle school with no sign support. She is on grade level and will be going to a regular college and become a contributing member of society.

Please do not make it even harder for people to access this critical, life changing technology!

Terri Charles
Mother of Kathy, 11, CI user

**Submitter :** Mr. R. Alan Burns **Date:** 09/16/2005

**Organization :** Society For Radiation Oncology Administrators

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached comment regarding CMS 1501-P HOPPS and 2006 payment rates

CMS-1501-P-621-Attach-1.DOC

**Attachment #621**

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention:CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8017

RE: CMS-1501-P HOPPS and 2006 Payment Rates

Dear Dr. McClellan:

The Society for Radiation Oncology Administrators (SROA) mission is to provide pro-active solutions for radiation oncology delivery through education, communication, collaboration and liaison with our members and with others who are involved with or who influence the overall care of our patients. Founded in 1983, the Society represents the greatest concentration of expertise in the field of radiation oncology management. Our membership is drawn from over five hundred (500) free standing, community hospital and university-based radiation oncology facilities.

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to :

Brachytherapy Services
The SROA does not support the proposed reduction in CPT codes 77778 and 57155. The proposed reduction for CPT code 77778 exceeds 42% ($530) and 57155 exceeds 66% ($503). This type of reduction can have a negative impact on patient access. While we understand that claims data has been reviewed, there is still a serious flaw. We plead with CMS to hold the reimbursement rate steady until the integrity of the data can be analyzed.

Stereotactic Services
CMS has proposed to eliminate G0338 and G0242. We support this elimination as there are currently CPT codes that describe this function.

Planning
77295 Three dimensional Planning or,
77301 Intensity Modulated Radiation Therapy Planning
and
Physics
77300 Basic Radiation Dosimetry
77370 Special Medical Physics Consultation

77315 Teletherapy Isodose Plan

Thank you for your prompt attention to this critical issue.

Sincerely,

R. Alan Burns
Chairman
Society for Radiation Oncology Administrators

**Submitter :** Ms. Connie Hoy **Date:** 09/16/2005

**Organization :** Lumenis Inc

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1501-P-622-Attach-1.PDF

CMS-1501-P-622-Attach-2.PDF

#622

LUMENIS

Enhancing Life. Advancing Technology.

September 16th, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8013

Sent by E-mail: www.cms.hhs.gov/regulations/ecomments

Re: **Reassignment of HCPCS code C9713 from New Tech APC 1525 to APC 0429**
**Reassignment of CPT code 52353 to APC 0429 and**

Dear Sir/Madam:

Lumenis is a global developer, manufacturer and seller of laser and light-based devices for medical, ophthalmic, aesthetic, dental and veterinary applications. We provide surgeons with multifunctional laser technology, enabling them to treat urological disorders with safe, effective, minimally invasive procedures. We appreciate the opportunity to comment on the reassignment of HCPCS code C9713 and CPT code 5234, which are frequently used for urology procedures with the holmium laser.

## REASSIGNMENT OF HCPCS CODE C9713 FROM NEW TECH APC 1525 TO APC 0429

CMS proposes to move HCPCS code C9713 (Non-contact laser vaporization of prostate, including coagulation control of intraoperative and post-operative bleeding) to the newly created APC 0429 (Level V Cystourethroscopy and other Genitourinary Procedures).

While we applaud the creation of APC 0429 for other cystourethroscopy procedures, we are extremely concerned that CMS's proposal to assign C9713 to APC 0429 is premature, as there is not sufficient data to justify its removal from New Technology APC 1525.

The reasons for keeping C9713 in New Tech APC 1525 are as follows:

1. CMS is basing its reassignment to a clinically appropriate APC based on only nine months of OPPS claims, as the HCPCS code C9713 became effective on April 1, 2004. CMS has left new technology procedures in New Tech APCs for longer periods of time, and we believe more time is needed to collect more robust data. The Program Transmittal detailing this new HCPCS code was not released until 3/30/04, with an 4/5/04 implementation date, so it is extremely unlikely that most hospitals even knew of this code for some time after its creation, meaning that the claims CMS has for C9713 are probably for much less than nine months of data.

Lumenis Inc.
2400 Condensa Street
Santa Clara, CA 95051 USA
t 408.764.3000
t 800.635.1313
f 408.764.3999
www.lumenis.com

LUMENIS

Enhancing Life Advancing Technology

2. An analysis of the 2004 OPPS claims data on C9713 shows wide swings in median cost depending on whether hospitals bill medical device revenue center codes (revenue center codes 270-279) to report the single-use laser fiber. Because this procedure can only be performed using single-use laser fibers, any claims that do not include medical devices are by definition inaccurate and significantly underestimate the cost of performing these procedures. When analyzing 2004 OPPS claims for C9713 that 1) include a medical device revenue center code and 2) screen out all those claims with medical device costs under $600, the median cost of C9713 claims increases to $3,066. This is a conservative screen on the device cost, as most laser fibers used in this procedure were priced at $895.

3. At the August 2005 APC Advisory Panel, a presentation was made on this issue, prompting discussion about hospitals' inconsistency in using the appropriate code for this procedure. Several Panel members said their hospitals were incorrectly coding these procedures and raised questions about the accuracy of the claims data. While the Panel ultimately agreed with CMS's proposal to move C9713 to APC 1525, this was based on an expectation that this code would end up in the APC anyway, not agreement on the accuracy of the OPPS data for C9713.

4. Removing C9713 from APC 0429 would only slightly shave APC 0429's median cost by $19 to $2,534. This minimal impact ensures that procedures remaining in APC 0429 (PCNL, BPH Laser Surgery) would not be adversely impacted by the removal of C9713.

5. Finally, under CMS's proposal, the payment rate for C9713 would fall by about 33%, from $3,750 to $2,511. We are concerned that this represents too much of an abrupt cut that could pose patient access concerns. It is also inconsistent with CMS efforts to mitigate payment reductions for device-related APCs. In the proposed rule, CMS places a 15% floor on the reduction in the median costs for device-dependent APCs in an effort to prevent dramatic cuts from year to year. We would urge CMS to consider this dampening mechanism for 2006. If CMS is convinced that a reassignment is justified, we would urge the agency to assign C9713 to another New Tech APC, such as New Tech APC 1524 ($3,000 to $3,500), as this would be consistent with the claims data collected thus far.

**Recommendations and CMS Requested Actions:**

- Keep HCPCS code C9713 in New Tech APC 1525 for one more year to allow for more claims data to be used in assigning this procedure to a clinically appropriate APC.
- As a minimally acceptable solution, we urge CMS to assign C9713 to New Tech APC 1524 (Level XIV - $3,000-$3,500) for CY 2006, as this tempered step would recognize the need for more claims to be used, while recognizing the $3,066 cost of C9713 claims using conservative device screens.

## REASSIGNMENT OF CPT CODE 52353 TO APC 0429

In the proposed rule, CMS created APC 0429 (Level V Cystourethroscopy and other Genitourinary Procedures). This new APC would hold a higher level of more device-intensive urologic procedures,

Lumenis Inc.
2400 Condensa Street
Santa Clara, CA 95051 USA
t 408.764.3000
t 800.635.1313
f 408.764.3999
www.lumenis.com

including laser surgery treatments for benign prostatic hyperplasia (BPH) and percutaneous nephrostolithotomy (PCNL).

We applaud the creation of this new APC, as it will better align payment rates for these cystourethroscopic procedures with resources they consume. These resources include capital equipment such as $130,000 laser consoles, $8,000 to $12,000 cystoscopes and nephroscopes. These procedures also use a wide range of single-use devices, such as ureteral balloon catheters, dilators, introducer needles, guidewires, drainage tubes and laser fibers for breaking up kidney stones or vaporizing and/or coagulating prostate tissue.

We would only recommend that CMS add the following code to APC 0429:

**CPT code 52353** - *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)*

Moving CPT code 52353 (ureteroscopic lithotripsy) to the newly created APC 0429 is justified based on the following reasons:

1. CPT code 52353 closely matches the other procedures in APC 0429 in terms of resource utilization and clinical homogeneity. This is evidenced by the fact that CPT code 52353 has been grouped for almost four years (2002 through 2005) with all the urology codes slated for assignment to APC 0429 (CPT codes 50080, 50081, 52647 and 52648).

2. By definition, CPT code 52353 is a procedure that requires the use of a ureteroscope (about $15,000), a cystoscope (about $8,000), and an holmium laser console (about $130,000) which provides the energy used in intracorporeal lithotripsy to break up kidney stones. The advent of the holmium laser has been revolutionary in the treatment of kidney stones, as it is extremely effective in fragmenting all varieties of stones in a minimally invasive fashion. Ureteroscopic lithotripsy also uses a wide range of single-use medical devices, including balloon dilatation catheters, ureteral sheaths, guide wires, ureteral catheters, stone retrieval baskets and laser fibers. The total cost of these devices can be well over $800 per procedure.

3. Like ureteroscopic lithotripsy, all the procedures now grouped in APC 0429 are urologic procedures using capital equipment and single-use medical devices. Like PCNL in APC 0429, ureteroscopic lithotripsy is performed on patients suffering from urinary stones lodged in the kidney and/or ureter by directly accessing the stone and pulverizing it via intracorporeal lithotripsy.

4. Ureteroscopic lithotripsy enjoys very high clinical outcomes, but can be costly due to the need for frequent repairs of the ureteroscope. Research shows that flexible ureteroscopes only can be used only 6 to 15 times before requiring expensive maintenance repairs to recondition the ureteroscope for use. A study published in the August 2003 issue of Urology (attached) showed a range of maintenance costs of $31,520 to $60,033 for 100 cases using different brands of ureteroscopes. This averages to a per procedure maintenance cost of $315-$600. It is likely most hospitals are not

Lumenis Inc.
2400 Condensa Street
Santa Clara, CA 95051 USA
t 408.764.3000
t 800.635.1313
f 408.764.3999
www.lumenis.com

LUMENIS

Enhancing Life. Advancing Technology.

accurately capturing the cost of these ureteroscope repairs when developing their OR charges, as most hospitals set their OR charges based on time and capital equipment costs, not on the maintenance costs for certain equipment. This suggests the OPPS median cost claims data on CPT 52353 may well underestimate the actual costs of this procedure by some $315-$600. With OPPS median cost for CPT code 52353 in 2004 at $2,150, actual costs incurred by hospitals for ureteroscopic lithotripsy may be closer to $2,465 to $2,750.

5. Even with the maintenance costs for ureteroscopes not likely being charged by hospitals, ureteroscopic lithotripsy still has the highest median cost ($2,150) of the nine procedures in CMS's proposed grouping of APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures). This is not enough on its own to justify a change but it shows that it already is on the cusp of the next level APC.

6. Moving CPT 52353 to APC 0429 would have a negligible impact on the median costs of APCs 0163 and 0429. The median cost of APC 0163 would fall by only $19 to $2,016, while APC 0429's median costs would drop by about $100 to $2,457. This means that other codes in APC 0163 and 0429 would not experience any payment disruptions, so there should not be any concern about unintended consequences of making this change.

**Recommendation and CMS Requested Action:**

- Assign CPT code 52353 from APC 0163 to the newly created APC 0429 (Level V Cystourethroscopy and other Genitourinary Procedures).

Thank you for your consideration.

Sincerely,

Connie Hoy
Director Global Regulatory and Quality Assurance

Lumenis Inc.
2400 Condensa Street
Santa Clara, CA 95051 USA
t 408.764.3000
t 800.635.1313
f 408.764.3999
www.lumenis.com

**Submitter :** **Dr. Robert Ancira** **Date: 09/16/2005**

**Organization :** **Uptown mental health center**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

FILE CODE: CMS-1501-P PARTIAL HOSPITALIZATION
Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates ? Proposed Rule

Our agency, UPTOWN MENTAL HEALTH CENTER - #194671, is a freestanding community mental health center in NEW ORLEANS, LOUISIANA. We serve approximately 150 patients on an annual basis. We employ approximately 10 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community.

We are requesting that the proposed 15% cut in the reimbursement for our program services be rescinded. The current payment rate is not sufficient to cover the costs needed for our intensive programs. Our costs are higher than hospitals who are able to spread their costs across other departments. Our patient acuity level is more intense than the hospital patients receiving one or two therapy sessions.

This service is especially needed for our rural communities who are not serviced by hospital programs. Additionally our state does not offer this program as a Medicaid service.

Please consider not implementing this drastic cut in Partial Hospitalization Program reimbursement when most outpatient costs are receiving a 3.5% increase in payment rates.

Our Mental Health Center has been non-operational since August 29, 2005 when hurricane Katrina devastated New Orleans. We were able to contact and bring over 40 of our patients to Baton Rouge, La., where with the help of local free standing Mental Health Centers, they are being housed and treated with a minimal amount of disruption. This catastrophic event has exemplified the value of this system of treatment for the mentally ill. When we are able to resume our operations in New Orleans, a reduced level of reimbursement would severely hamper our ability to resume our care of the New Orleans mentally ill population and may possibly result in our having to cease operating.

Thank you for your attention. Robert Ancira, MD ? Medical Director, UMHC.

**Submitter :** Mr. Roy C. Vinson
**Organization :** Heart Hospital of Austin
**Category :** Hospital

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment Letter

CMS-1501-P-624-Attach-1.DOC

CMS-1501-P-624-Attach-2.DOC

Attachment #624

HEART HOSPITAL of AUSTIN

September 16, 2005

Administrator Mark B. McClellan
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

Re: 2005 Proposed Hospital Outpatient Prospective Payment System, CMS-1501-P
Proposed Payment Changes for Device-Dependent APCs (Section IV. A.)

Dear Administrator McClellan:

Heart Hospital of Ausin welcomes the opportunity to comment on CMS's proposed rule on the *Hospital Outpatient Prospective Payment System* for 2006. In this letter, we offer our perspectives and recommendations on the proposed payment rates for APC 107 (Insertion of implantable cardioverter-defibrillator [ICD] pulse generator only) and APC 108 (Insertion of ICD system).

Since 1999, Heart Hospital of Austin has been committed to providing quality heart care to all Central Texas communities. We are the life-line for many rural area physicians and their patients, especially in times of heart emergencies. We are licensed as general acute care hospital and provide in patient and well as outpatient services. Annually, we treat over 200 patients in need of implantable defibrillators, and have historically treated those patients as one-day stay inpatients (both AICD or Bi-Ventricular) AICD. We now use Interqual criteria which recategorizes the same services as outpatient. This allows for a much lower level of reimbursement thought most of the procedural costs (device cost and cath lab services) remain consistent.

Outpatient payment rates for ICD procedures have decreased considerably since the pass-through payments expired in 2002. Those decreases have resulted in inadequate payment rates that often do not cover our true costs in performing these procedures. The inadequate payment rates seem to be attributed to Medicare's current inability to accurately estimate hospital costs for procedures using advanced devices, such as ICDs.

To assure continued access to ICD therapy in the less costly outpatient setting, we support the August 2005 APC Advisory Panel's recommendation to use 100% of the 2005 payment rate, plus the standard OPPS hospital base rate increase, as a floor for 2006 payments for APCs 107 and 108. Longer term, we urge CMS to seek a permanent solution for obtaining data that accurately reflect true hospital costs when setting payment rates for procedures utilizing advanced medical technologies. The lifesaving therapy associated with ICDs has been proven through various clinical trials, and it is important that Medicare establishes a payment setting mechanism that is fair and equitable to promote the efficient delivery of these services without limiting access to care.

We look forward to continuing to work with CMS on outpatient prospective payment system policy issues to ensure the long-term viability of America's healthcare system and timely patient access to innovative technologies in the outpatient setting.

Sincerely,

Roy C. Vinson

Roy C. Vinson
President

**Submitter :** Dr. Thomas Huff

**Organization :** Wound Healing Center at Harlingen Medical Center

**Category :** Physician

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am submitting this public comment to bring to your attention to an error in the proposed rule, CMS-1501-P, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft. In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent. In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product. However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84 and Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32. There may have been some confusion in the proposed rule because the products are reimbursed in the physician?s office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

**Submitter :** Mr. John Dahl

**Organization :** Good Samaritan Hospital

**Category :** Health Care Professional or Association

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

To Whom It May Concern:

I am writing to express my concerns with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule?, published in the Federal Register on July 25, 2005.

In the proposed rule, the payment rates for procedures involving ICDs were significantly decreased. As a health care provider of these services to Medicare beneficiaries, these payment reductions are a serious concern. Changes should be made to the 2006 proposed payment rates for ICDs that are more closely aligned with the real cost of providing these services. The 2006 proposes a 14.1% payment decrease relative to 2005 payments for ICD APCs 0107 and 0108 resulting in an unsustainable financial burden for our institution. The resulting APC rates are lower than our institution?s cost for the device itself, leaving us with an out-of-pocket loss for device acquisition and no payment for the procedure. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To fix this problem, we request that CMS base the 2006 payment rates for ICD implant procedures on the 2005 payment rates plus the 3.2% hospital update. I understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates, while not entirely adequate, would be more in line with our facility?s actual cost of performing these services.

In the proposed rule, CMS requested comments on the February 2005 APC Advisory Panel recommendation to increase the number of single procedure claims available for rate setting for APCs 0107 and 0108. Although the scenarios displayed in the proposed rule increase the number of single procedure claims, single procedure claims have shown no ability to provide appropriate payment in the last five years and we are not able to support this proposal.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization devices (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase, the move to the new APC actually equates to a lower rate of reimbursement than in 2005 due to the change in the status indicator. In the proposed rule the status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

The assignment of a status indicator ?T? does not make sense in an APC where the device cost is 90% of the procedure. There is not a 50% reduction in acquisition cost when implanting it at the same time as the device resulting in an out-of-pocket loss to the hospital. To address this problem, we request that CMS retain the ?S? status indicator for the left sided lead APC.
Thank you for the opportunity to comment.

Sincerely,

John Dahl, Director
Cardiac & Vascular Institute
Good Samaritan Hospital

**Submitter :** Dr. Judith Baker

**Organization :** The Resource Group

**Category :** Health Care Industry

**Date:** 09/16/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1501-P-627-Attach-1.DOC

#627

The Resource Group

Dallas - Cleveland

*Providing practical answers to complex problems for over thirty years*

Reply to:
P O Box 70
Pickton, TX 75471

September 16, 2005

Dr. Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8018

**Re: Comments on CMS-1501-P (Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule)**

Dear Dr. McClellan:

The Resource Group welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule" as published in 70 Fed. Reg. 42674 on July 25, 2005 ("Proposed Rule"). Resource Group is a healthcare consulting firm with a specific focus on resource consumption and its relationship to payment methodologies among and between the various sites of care. We consult nationally and have the opportunity to observe the perplexity existing among providers concerning payment issues. Thus we speak from a broad perspective of provider views.

*Re B. "Non-Pass-Throughs"*

## Background

For 2006 (and presumably for 2007), CMS proposes a percentage of average sales prices as an adjustment to cover the pharmacy costs hospitals incur for handling separately payable drugs and biologicals. In addition, CMS proposes to establish three distinct C-codes for drug handling categories and to instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description which best reflects the service the hospital provides to prepare the product for administration to a patient. CMS intends to track and collect hospital charges for these C-codes for the next two years. CMS would then consider basing payment for the corresponding drug handling APCs on the charges reduced to costs in CY 2008, similar to the payment methodology for other procedural APCs. We have two comments concerning the proposed drug handling categories.

**CMS Should Ensure That the Description Within Category 3 of the Proposed Drug Handling Categories In Table 24 Is Clarified to Specifically Describe Certain Characteristics of Those Specialty IV or Agents That Require Special Handling In Order To Preserve Their Therapeutic Value**

Regarding Category 3 of the proposed drug handling categories (see Table 24), The Resource Group asks CMS to clarify the phrase "Specialty IV or Agents requiring special handling in order to preserve their therapeutic value . . . .". Specifically, we request that "special handling in order to preserve their therapeutic value" should be further described as including those specialty IV or agents (e.g. monoclonal antibodies and other biologic response modifiers) that require special storage conditions such as cold-chain management (e.g. refrigerated conditions) and that have a limited life upon reconstitution (e.g. two to forty-eight hours).

We ask CMS to include this clarification in the final rule.

**CMS Should Consider Increasing the Number of Proposed Drug Handling C-Code Categories to Allow for Greater Specificity in Tracking and Collecting Data**

In the June 2005 Report to the Congress, MedPAC recommended six drug handling descriptions. CMS has collapsed the six MedPAC drug handling descriptions into three proposed C-code categories (see Table 24). The proposed categories two and three presently contain a wide range of products. It will not be a simple task for the hospital pharmacy to equate their charges to these wide ranges. In addition, the resulting data will not yield the specificity required for optimum future rate-setting.

Consequently we request that CMS consider expanding the number of C-code handling charge categories.

We appreciate the opportunity to comment upon this Proposed Rule. Please contact us at 903-866-3614 or at jbaker@consultresourcegroup.com if you have questions about this matter.

Yours truly,

Judith J. Baker, PhD, CPA
Executive Director, The Resource Group
Editor, *Journal of Health Care Finance*

**Attachment:**

## Table 24 – Proposed CY 2006 Drug Handling Categories, C-Codes, and APCs

| Drug Handling Category | C Code | Drug Handling APC | Description |
|---|---|---|---|
| Category 1 | CWWWW | WWWW | • Orals (oral tablets, capsules, solutions) |
| Category 2 | CXXXX | XXXX | • Injection/Sterile Preparation (draw up a drug for administration)<br>• Single IV Solution/Sterile Preparation (adding a drug or drugs to a sterile IV solution) or Controlled Substances<br>• Compounded/Reconstituted IV Preparations (requiring calculations preformed correctly and then compounded correctly) |
| Category 3 | CYYYY | YYYY | • Specialty IV or Agents requiring special handling in order to preserve their therapeutic value or Cytotoxic Agents, oral (chemotherapeutic, teratogenic, or toxic) requiring personal protective equipment (PPE)<br>• Cytotoxic Agents, (chemotherapeutic, teratogenic, or toxic) in all formulations except oral requiring personal protective equipment (PPE) |

Source: "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates"; Table 24. 70 Fed. Reg. 42730 (July 25, 2005).